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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,462	03/03/2006	Yves Mayeresse	VB60410	1403

20462

7590

08/08/2008

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

08/08/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US\_cipkop@gsk.com

# Office Action Summary

**Application No.**

10/533,462

**Applicant(s)**

MAYERESSE, YVES

**Examiner**

Rodney P. Swartz, Ph.D.

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's Response to Office Action, received 6 May 2008, is acknowledged. Claims 12, 14, 18, 22, and 38 have been amended.
2. Claims 1-40 are pending and under consideration.

### **Rejections/Objections Withdrawn**

3. The objection to claim 12 is withdrawn in light of the amendment of the claim.
4. The objection to claim 18 is withdrawn in light of the amendment of the claim.
5. The objection to claim 22 is withdrawn in light of the amendment of the claim.
6. The rejection of claim 38 under 35 U.S.C. 112, second paragraph, as being indefinite for "whole Diphtheria antigen", is withdrawn in light of the amendment of the claim.
7. The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for concentration, is withdrawn.
8. The rejection of claims 13, 19-21, 34, 35, and 40 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from rejected/objected claims, is withdrawn.

### **Rejections Maintained**

9. The provisional rejection of claims 23-33, 36-39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6, 14, 15-18, and 20 of copending Application No. 10/533,464, is maintained.

Applicant argues that the rejection is the only one remaining and therefore should be withdrawn.

The examiner has considered applicant's argument, but does not find it persuasive because the provisional rejection is not the only rejection remaining.

### **Claim Rejections - 35 USC § 112**

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10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for preserving an agent and compositions comprising said agent, which retain  $\geq 40\%$  of the antigenicity, activity, immunogenicity, or combination thereof of said agent wherein the stabilizing agent is 3.5-25% weight/volume, does not reasonably provide enablement for any/all concentrations of stabilizing agent less than 3.5% weight/volume. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - Claims 1-13 and 15-22 are drawn to a method of preserving an agent utilizing any concentration of stabilizing agent, determined by either weight/volume, or volume/volume. Claim 14 is drawn to the same method utilizing the concentration of 5-10% (no restriction to w/vol, or vol/vol). Claims 23-35 and 39-40 are drawn to a composition/kits obtained by the method of claim 1, determined by either weight/volume, or

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volume/volume. Claims 36-38 are drawn to a method of making a vaccine comprising reconstitution of the composition of claim 23, determined by either weight/volume, or volume/volume.

The state of the prior art, as evidenced by the discussion in the instant specification indicates that preserving an agent's activity  $\geq 40\%$  without bubbling or freezing was unknown at the time of filing (U.S. Pat. No. 6,306,345; U.S. Pat. No. 5,766,520).

The predictability or lack thereof in the art - there is a lack of predictability in the art for the types/concentrations of stabilizing agents which would maintain the required  $\geq 40\%$  activity of the agent.

The amount of direction or guidance present in the instant specification is insufficient for the broad scope of the instant claims. The specification examples utilized stabilizing concentration of 3.15% to 10% weight/volume.

The quantity of experimentation necessary utilizing  $\leq 3.15\%$  determined by other than weight/volume constitutes merely an invitation to experiment without a reasonable expectation of success.

### **Conclusion**

12. No claims are allowed.
13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

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The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

August 8, 2008